By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 766741 R000

Manufacturer: TIDI Products, LLC

Address:
570 Enterprise Drive
Neenah
Wisconsin
54956
USA

Single Registration Number: US-MF-000012287

EU Authorised Representative: MDSS GmbH

Address:
Schiffgraben 41
30175 Hannover
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-12-06**

Current Issue Date: **2024-08-29**

Starting Validity Date: **2024-08-29**

Expiry Date: **2028-12-05**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile Securement Devices	Class Is
Sterile Instruments and Equipment Covers	Class Is
Sterile Surgical Drapes	Class Is
Sterile Urology Drainage and Fluid Collection Devices	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-12-06	3636456	Issued
2024-03-07	30079921	Supplemented – Addition of Class Is device group Sterile Urology Drainage and Fluid Collection Devices
2024-05-31	30181570	Restricted – Removal of device "Sterile Scalpels with Safety Systems, Single-Use" no longer placed on the market and removal of related critical subcontractors.
Current	30247229	Amended – Addition of subcontractors for sterile barrier packaging and sterilization.

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